FINAL REPORT ON THE STUDY OF PATIENT SAFETY IN MARYLAND

EXECUTIVE SUMMARY

Assuring patient safety is an ongoing concern, however recognizing the issue exists, openly discussing, and systematically analyzing adverse events and near misses, and sharing this information is an important first step.

In 2001, the Maryland General Assembly charged the Maryland Health Care Commission (MHCC), in cooperation with the Department of Health and Mental Hygiene (DHMH), with studying the feasibility of developing a system for reducing the incidence of preventable adverse medical events in Maryland, including but not limited to a system of reporting such incidents. The recommendations for the design of a patient safety system in Maryland are built upon the proposed suggestions in the Interim Report, issued in 2002.

Developing a 'patient safety system' for a medical facility, let alone an entire state, is a daunting task. Other states have passed patient safety initiatives piecemeal rather than taking a comprehensive approach. For example, twenty states have opted for mandatory reporting of certain adverse events, while others have instituted laws regulating health care professionals (California's nursing staff ratios and New York's restrictions on hours worked by residents). Employers (e.g., Leapfrog Group) have also been involved in patient safety efforts using selective contracting to promote safe practices that are often seen as cost effective in the long run. While all of these initiatives are notable, a comprehensive initiative promoting a common philosophical approach to the issues related to patient safety has been missing in most state efforts.

The recommendations detailed below attempt to establish a common philosophical approach for Maryland initiatives. This approach, similar to the VA and aviation industry, emphasizes the creation of a culture which is attentive to issues of patient safety, encourages and rewards (or at least does not punish) those who bring adverse events and near misses to the attention of leadership for investigation. It promotes the use of Root Cause Analysis as a tool for the evaluation of errors or potential errors and fosters systems changes, which may prevent other similar errors. The approach outlined in this report does not address intentionally unsafe acts, which are within the purview of the existing health occupation boards. Instead, the focus is on improving the entire system of health care delivery, based on evidence that indicates that the majority of errors are due to system failures.

In order to develop final recommendations on Maryland's patient safety initiatives, the MHCC explored several global issues. Input on these issues was elicited from the Maryland Patient Safety Coalition as well as national experts. Several questions formed the basis for the Coalition's deliberations:

1. Should the patient safety system focus on accountability, quality improvement, or both (i.e., should the system be punitive or nonpunitive in emphasis)?

2. Should the patient safety reporting system be voluntary or mandatory or include elements of both approaches?
3. Should information collected be protected from legal discovery to be used for quality improvement or should it be made public for consumer accountability?

Based on information obtained from national leaders in health care and patient safety, a thorough literature review, and feedback from members of the Maryland Patient Safety Coalition, the Commission recommends that the Maryland patient safety system be based on a three-pronged approach which includes: (1) the establishment of the Maryland Patient Safety Center; (2) the use of the State's regulatory authority to promote systems improvements; and (3) limited mandatory reporting (see Diagram A).

Essential to the success of this model is the creation of a system that focuses on quality improvement, encourages voluntary reporting without fear of blame or reprisal, and protects against legal discovery. While the focus of this report is centered on the patient safety activities and initiatives of hospitals and nursing homes, the ultimate goal is to involve all health care facilities (including ambulatory surgery centers and assisted living facilities) in a comprehensive, systemic effort to improve patient safety and provide high quality health care.

I. **Develop Maryland Patient Safety Center (MPSC)** - The Maryland Patient Safety Center should form the foundation of the patient safety effort. The MPSC will provide an institution at the state level similar to the national patient safety center recommended in the 1999 IOM report. Its purpose is to provide a means to share information between facilities without fear of reprisal and to exchange ideas about how to address adverse events and improve processes of care (see Diagram B).

- The MPSC should serve as the data repository center for voluntarily reported adverse events and near misses and as the primary coordinator for educational activities related to building consensus around patient safety issues.

- Support for the MPSC and its activities will be developed through a grassroots effort to build consensus around patient safety initiatives. An Advisory Board, comprised of representatives from health care industry associations, professional societies and associations, the Medicare Quality Improvement Organization (The Delmarva Foundation), the Maryland Health Care Commission (MHCC), and other interested groups, will encourage health care professionals and facilities to participate in the voluntary reporting and educational activities of the Center.

- Legislation should be introduced in the 2003 General Assembly Session amending the Maryland statute to include the MPSC under the definition of a medical review committee, so that reports will be protected from discovery. Existing reporting protections for civil immunity that are available to all health care professionals reporting to all health occupation boards and medical review committees should be granted to those who report to the MPSC.

- The MPSC should be incorporated within a non-regulatory body to establish trust with facilities and providers to encourage reporting. In fact, there should be a "firewall" between the licensing and investigating functions of DHMH and voluntary reporting to the MPSC.

- Financial resources to establish a MPSC need to be considered. After consultation with the sponsor of the enabling patient safety legislation, the MHCC supported an application by the University of Maryland's Organized Research Center on Health Policy to the federal Agency for Healthcare Research and Quality (AHRQ) to fund the development of MPSC for a three-year period at $500,000 per year. This grant, if awarded, will provide funding to establish a Center. It will also provide an opportunity to test whether a grassroots consensus building approach can make a voluntary system of reporting work statewide. Initial reporting will be limited to hospitals and nursing homes. If the AHRQ grant is not funded, the State should pursue other grants from private foundations.

II. **Promote Data Systems and Advanced Technologies** – State regulatory agencies should give priority to patient safety initiatives that improve the system of delivering health care.

- The literature indicates that most adverse events are attributable to systems of care, not the individual practitioners committing an intentionally unsafe act.

- Several initiatives have proven effective and have been recommended to reduce the occurrence of adverse events and improve patient safety. Technologically–advanced and/or resource intensive practices shown to be effective in reducing the occurrence of adverse events should be adopted by facilities. They include computerized physician order entry (CPOE), bar coding, and the use of intensivists in intensive care units.

- Two state agencies, the Health Services Cost Review Commission (HSCRC) and the Maryland Health Care Commission (MHCC) have the opportunity to give priority to patient safety in their regulatory decisions.

    - HSCRC – The HSCRC approves hospital rates in the State. Research indicates major systems initiatives such as CPOE can vary in cost per hospital depending on the size of the hospital. Currently, at least twelve of Maryland's forty-seven acute care hospitals have some level of CPOE or are in the process of implementing it (according to the Maryland Patient Safety Coalition survey). Some hospitals are implementing CPOE in stages to spread the costs. Subject to the requirements of the HSCRC, facilities should have the opportunity to request an increase in rates based on the capital expenditures associated with introduction of advanced technologies such as electronic medical records and CPOE that have been linked with patient safety improvements. The HSCRC should consider whether these initiatives will be cost-neutral in the long run by creating greater efficiency and decreasing length of stay due to complications and reducing malpractice liability costs.

- MHCC – The MHCC has at least two vehicles that should be used to prioritize safety issues:
  1) Performance Evaluation Guides – These Guides should inform consumers regarding technologies available to improve patient safety and facilities that have implemented them. This would inform the consumer's selection process. For example, the Guide could indicate the presence or absence of bar coding, electronic medical records or CPOE at a particular facility. The Guides could also indicate whether a hospital or nursing home had contracted to participate in reporting to the proposed Maryland Patient Safety Center.

  2) State Health Plan and Certificate of Need Process – The MHCC should incorporate approval standards into the State Health Plan that give priority to projects designed to improve patient safety. This would provide guidance in Certificate of Need reviews for new projects.

  The MHCC has already incorporated certain evidence based practices into the Plan Chapter on Specialized Cardiac Services – Cardiac Surgery and Therapeutic Catherization Services (COMAR 10.24.17) which set minimum volume standards for programs doing open heart surgery and angioplasty.

- Initiatives requiring minimal resources should be encouraged to be implemented in a relatively short period of time. They include those listed on pages 36 to 40 of this report.

III. **Implement Strengthened Hospital Patient Safety Programs and Limited Mandatory Reporting to the Department** - The proposed regulations were developed in consultation with the Maryland Hospital Association, malpractice carriers, a number of hospital representatives, and the Maryland Society for Healthcare Risk Management as well as the Assistant Attorney General representing OHCQ.

- Risk Management regulations should be revised to strengthen hospital Patient Safety Programs, specifically the setting of standards for reporting of adverse events and near-misses, performance of root cause analysis, and other evaluations and trending of events and near-misses to identify patterns. Since 1988, Maryland has had risk management regulations that have required some internal incident and evaluation procedure; however, these need to be strengthened and revised.

- Regulations need to be implemented to increase external and public accountability. Those events that result in death or serious disability should be reported to the Department with the corresponding root cause analysis. The Department should review the event and the root cause analysis to ensure that the hospital has responded appropriately. The root cause analysis and any medical review committee information should remain confidential and non-disclosable. Only deficiencies resulting from a complaint investigation would be publicly available.

- The proposed regulatory changes, based on recommendations from the 1999 IOM study *To Err is Human*, JCAHO Accreditation Standards for Hospitals, the Veterans Administration Patient Safety program, and the National Quality Forum's *Consensus Report of Serious Reportable Events*, are intended to accomplish the following:

    - Define and categorize events based on actual occurrence and severity;
    - Require internal reporting of certain events;
    - Encourage reporting of near-misses;
    - Specify the type of response to serious adverse events and near-misses;
    - Define root cause analysis (RCA) and require an RCA for certain events;
    - Emphasize that Maryland law provides for protection of event information (confidentiality and non-discoverability) under certain conditions;
    - Require reporting of only those events that result in death or serious disability to the Department and provide for confidentiality protections;
    - Require notification to a patient and, when appropriate, that patient's family of an outcome of care that differs significantly from an anticipated outcome;
    - Require the hospital to provide notice to a patient and family that complaints can be filed with the Department; and
    - Generally update language to be consistent with JCAHO terminology.

- Regulations should be promulgated in the near future to require such reporting by other types of health care providers, such as nursing facilities and ambulatory care centers.

IV. **Other Issues**

- Nurse Staff Ratios – State should continue to monitor ongoing research.

  The MHCC reviewed literature on nursing staff ratios and other quality assurance initiatives and concluded that workforce mandates and their consequences are not conclusive. In Maryland, minimum nursing personnel staffing levels of bedside care for comprehensive care facilities are required by regulations. Also, OHCQ maintains the authority to issue staffing levels for hospitals, if necessary. While higher nurse-to-patient ratios have been shown to improve outcomes, there is still debate about impact of requiring specific ratios on the health care system as a whole with respect to health care costs, access to care, and manpower shortages. For that reason, the MHCC declines to endorse mandatory ratios for hospitals at this time and instead recommends monitoring outcomes in states that do mandate ratios. Consideration should also be given to the appropriateness of ratios given the level of patient's acuity and whether the ratios apply to actual bedside time.

- Maryland Patient Safety Coalition – The Patient Safety Coalition should continue as an effort to provide leadership and expertise in addressing patient safety issues.

  Ongoing meetings with leaders of Maryland facilities, State Boards of Health Occupations, and professional societies and associations will foster and promote a commitment to

improving the quality of health care and patient safety.

- The Maryland Health Care Commission – MHCC should continue to monitor evolving patient safety initiatives.

The MHCC should watch developments that are being implemented by other states as well as any national initiatives including Congressional requirements as well as programs undertaken by the Department of Veterans Affairs and the Agency for Healthcare Research and Quality.

The MHCC should have a role in the development of the proposed three-pronged approach to patient safety in Maryland and should periodically review the progress of the proposed effort.

Future patient safety activities in Maryland should be done in collaboration with national initiatives (such as the NQF and JCAHO).